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09/890,532	04/15/2002	Kurt Burger	R.35252	3306

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RONALD E. GREIGG
GREIGG & GREIGG P.L.L.C.
1423 POWHATAN STREET, UNIT ONE
ALEXANDRIA, VA 22314

EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,532

Applicant(s)

BURGER ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. The finality of the rejection of the Office action dated 10/19/2005 is withdrawn in view of the new grounds of rejection presented in the instant non-final office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 15-23 and 29-32 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Fluid communication provided between the interior of the vessel and the chamber holding the vessel is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. Also the feature that the same gas provided for the sterilization of the inside of the vessel is used for sterilization of the outside of the vessel is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Note as discussed on page 10, lines 8-21, the "leakage groove" is essential to the invention, if not, the required pressures ratios would not be capable of being generated using only the disclosed gas source (6) and pump (9). The instant disclosure fails to convey to one of ordinary skill in the art at the time the invention was filed that the invention can be practiced without the "leakage groove" and/or fluid communication between the vessel and chamber. As a result, undue experimentation would be required to practice the invention in any other manner..

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 15-23 and 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 15, while the claim recites a method of sterilizing an interior region and exterior region of a vessel using selective excitation of plasma at different times and separate control of the pressures inside and outside the vessel, the claim is indefinite, unclear and/or incomplete because it is devoid of positively recited method steps that provide the selective excitation of plasma in the interior and exterior of the vessel.

Claims 15-23 and 29-32 are indefinite as a result of their dependency on claim 15.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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8. Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Fayet et al.(WO 97/44503) in view of either of Menashi (US 3,383,163) or Darras (WO 99/49991 or US 6,919,114).

The reference of Fayet et al. discloses a method of sterilizing vessels wherein selective excitation of the plasma is effected in the interior region of the vessel by separate control of the pressure inside and outside the vessel (1) (See page 1, lines 10-15, and Figure 1). The plasma excitation takes place as a result of a pressure sufficiently below atmospheric pressure (See page 5, lines 18-22).

Claim 15 differs by reciting that the exterior region of the vessel is also sterilized at a different time.

The references of Menashi and Darras all disclose that it is known and/or desirable to treat or sterilize the exterior region of a vessel with a plasma excited with electromagnetic oscillations. The reference of Menashi discloses sterilization of both the interior and exterior of the vessel (See Figure 4 and related text). The reference of Darras discloses that it is known in the art to separately treat the exterior region and interior region of a vessel (See column 3, lines 39-49 of US 6,919,114).

In view of either of these references, it would have been obvious to one of ordinary skill in the art to alter the pressure conditions within the system of the primary reference for the known and expected result of also selectively treating the exterior surface of the vessel, since it is known and desirable in the art to treat both the interior and exterior regions of a vessel as evidenced by the references of Menashi and Darras. Treating the vessel at different times by selective control of the pressures for exciting the plasma would be desirable as evidence by the

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disclosure of Fayet et al. which discloses that selective control of the pressure reduces energy consumption of the system (See page 3, lines 1-11, and page 4, lines 18-29).

With respect to claim 16, the resulting method would include providing a vessel within chamber (2) and supplying a gas (6') suitable for excitation.

With respect to claim 17, the required gas pressures are maintained between the vessel interior and chamber (See page 5, lines 18-22).

With respect to claims 18 and 29, the chamber is evacuated prior to introducing the gas (See page 8, lines 18-19).

With respect to claim 19, gas would be provided to the chamber when exciting the exterior region of the vessel as suggested by the modification of the reference of Fayet et al. as discussed above.

With respect to claims 20 and 21, the resulting method would include providing a vessel within chamber (2) and supplying a gas (6') suitable for excitation and the required gas pressures are maintained between the vessel interior and chamber (See page 5, lines 18-22).

With respect to claims 22, 23, 31 and 32, gas would be provided to the chamber when exciting the exterior region of the vessel as suggested by the modification of the reference of Fayet et al. as discussed above.

9. Claims 24, 25, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser et al.(US 3,851,436) in view of Hoeck (US 4,544,529) or Schulte (US 2,501,193).

The reference of Fraser et al. discloses a plasma sterilization device that includes a chamber (1'), a conduit means (5'') connected via feed line (5') with a gas supply (3) located

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outside the chamber (1'). The device includes a pump (13) connected to the chamber (1') and a plasma source (6',8') mounted on the outside of the chamber (1') and operable to excite plasma in the chamber (1').

With respect to claim 24, while the reference of Fraser et al. discloses a structure for supporting vessel (2) while holding the vessel within the chamber and also connecting the vessel to the plasma gas source (See Figure 2), claim 24 differs by reciting that the vessel is supported on a cone with a leakage groove.

The reference of Hoeck (US 4,544,529) disclose a structure for holding a container while exposing the container to a sterilization gas wherein the holder includes a cone (15) that includes a groove forming member (13) such that gas can flow from the interior of the container to the exterior of the container (See Figure 1 and column 4, lines 1-26).

The reference of Schulte disclose a structure for holding a container while exposing the container to a sterilization gas wherein the holder includes a cone (8) that includes a groove forming member (11) such that gas can flow from the interior of the container to the exterior of the container (See Figure 2).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the cone or funnel structure of the reference of Hoeck or Schulte as a device for supporting and communicating the plasma gas with the interior of a vessel in the system of the primary reference when sterilizing vessels with a single opening for the known and expected result of providing an art recognized means for allowing a sterilization gas to contact the interior and exterior of a vessel to be sterilized.

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With respect to claim 25, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to optimize the opening formed by the grooves for the known and expected result of ensuring that enough back-pressure is created within the container interior to ensure that the gas contacts the interior of the container a sufficient amount of time to ensure sterilization of the interior of the container.

With respect to claim 26, the use of endless chain conveyors is well known in the art for allowing a plurality of vessels to be run through

With respect to claim 27, both the references of Hoeck and Schulte disclose the use of the cones structures in combination with carriers or boxes (See element (3) of Hoeck and element (3) of Schulte) that include flange portions that allow the cones to be communicated with a source of sterilization gas.

With respect to claim 28, the device is capable of treating plastic or glass vessels.

10. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser et al.(US 3,851,436) in view of Hoeck (US 4,544,529) or Schulte (US 2,501,193) taken further in view of Schroeder et al.(US 6,328,928 or WO 98/30491).

The combination of the references of Fraser et al. with either Hoeck or Schulte has been discussed above.

Claim 26 differs by reciting that the system employs a chain link conveyor.

The reference of Schroeder et al. discloses that is it conventional in the art to employ endless chain conveyors for conveying a plurality of vessels with a sterilization system (See column 2, lines 10-14).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an endless chain conveyor with the system of the modified primary reference for the known and expected result of allowing a plurality of vessels to be passed through the sterilization system so as to avoid the need to manually open and close the chamber between sterilization cycles. Use of a conveyor system would increase the efficiency and number of vessels that can be sterilized when compared to a manual operation.

11. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fayet et al. (WO 97/44503) in view of Hoeck (US 4,544,529) or Schulte (US 2,501,193).

The reference of Fayet et al. discloses a plasma sterilization device that includes a chamber (2), a conduit means (3') connected via feed line with a gas supply (6') located outside the chamber (2). The device includes a pump (vacuum) connected to the chamber and a plasma source (5) mounted on the outside of the chamber (2) and operable to excite plasma in the chamber (2).

With respect to claim 27, both the references of Hoeck and Schulte disclose the use of carriers or boxes (See element (3) of Hoeck and element (3) of Schulte) that include flange portions that allow the cones to be communicated with a source of sterilization gas.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide a carrier box to support and communication a plurality of vessels with a gas source as is convention in the art of sterilization as evidenced by the references Hoeck and Schulte.

With respect to claim 28, the device is capable of treating plastic or glass vessels.

12. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fayet et al.(WO 97/44503) in view of Schroeder et al.(US 6,328,928 or WO 98/30491).

The reference of Fayet et al. discloses a plasma sterilization device that includes a chamber (2), a conduit means (3') connected via feed line with a gas supply (6') located outside the chamber (2). The device includes a pump (vacuum) connected to the chamber and a plasma source (5) mounted on the outside of the chamber (2) and operable to excite plasma in the chamber (2).

Claim 26 differs by reciting that the system employs a chain link conveyor.

The reference of Schroeder et al. discloses that is it conventional in the art to employ endless chain conveyors for conveying a plurality of vessels with a sterilization system (See column 2, lines 10-14).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an endless chain conveyor with the system of the primary reference for the known and expected result of allowing a plurality of vessels to be passed through the sterilization system so as to avoid the need to manually open and close the chamber between sterilization cycles. Use of a conveyor system would increase the efficiency and number of vessels that can be sterilized when compared to a manual operation.

Response to Arguments

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13. Applicant's arguments with respect to claims 15-23 and 29-32 have been considered but are moot in view of the new ground(s) of rejection.

14. With respect to the rejection of claims 24, 25, 27 and 28 under 35 USC 103 over the combination of the references of Fraser et al. and Hoeck or Schultze, Applicants argue (See pages 10-12 of the response dated 1/18/06) that none of Fraser et al., Hoeck and Schultze teaches or suggests the apparatus recited in claims 24 or 27. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). With respect to the rejection of claim 26 under 35 USC 103 over the combination of the references of Fraser et al. and Hoeck or Schultze taken further in view of Schroeder, Applicants argue (See pages 12-13 of the response dated 1/18/06) that none of Fraser et al., Hoeck, Schultze and Schroeder teaches or suggests the apparatus recited in claim 26. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

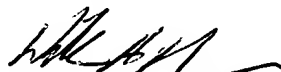
Conclusion

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



William H. Beisner
Primary Examiner
Art Unit 1744

WHB